Guidelines for Medical Necessity Determination for Enteral Nutrition Products

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information MassHealth needs to determine medical necessity for enteral nutrition products. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and/or state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 409.000 and 450.000 and Subchapter 6 of the *Durable Medical Equipment Manual* for information about coverage, limitations, service conditions, and other prior-authorization requirements.

MassHealth reviews requests for prior authorization on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

Section I. General Information

Enteral nutrition is defined as supplemental feeding that is provided via the gastrointestinal tract by mouth (orally), or through a tube, catheter, or stoma that delivers nutrients distal to the oral cavity, for the purpose of alleviating, correcting, or preventing the worsening of medical conditions that place the patient at nutritional risk. A member is considered to be at nutritional risk if he or she has actual, or potential for developing, malnutrition, as evidenced by clinical indicators, the presence of chronic disease, or increased metabolic requirements due to impaired ability to ingest or absorb food adequately.

Section II: Clinical Criteria

A. Coverage Criteria

MassHealth determines medical necessity for enteral nutrition products by considering multiple criteria that include, but are not limited to, the following.

1. Enteral nutrition, whether orally or by tube feeding, is used as a therapeutic regimen to prevent serious disability or death in a member with a medically diagnosed condition that precludes the full use of regular food.
2. The member presents clinical signs and symptoms of impaired digestion, malabsorption, or nutritional risk, as indicated by the following anthropometric measures:
   a. weight loss that presents actual, or potential for developing, malnutrition as defined below:
      1. in *adults*, showing involuntary or acute weight loss of greater than or equal to 10 percent of usual body weight during a three-to-six-month period, or body mass index (BMI) below 18.5 kg/m^2;
      2. in *neonates, infants,* and *children*, showing:

- very low birth weight (LBW) even in the absence of gastrointestinal, pulmonary, or cardiac disorders;
- a lack of weight gain, or weight gain less than two standard deviations below the age-appropriate mean in a one-month period for children under six months, or two-month period for children aged six to 12 months;
- no weight gain or abnormally slow rate of gain for three months for children older than one year and/or documented weight loss that does not reverse promptly with instruction in appropriate diet for age; or
- weight for height less than the 10th percentile; and

b. abnormal laboratory tests pertinent to the diagnosis.

3. The risk factors for actual or potential malnutrition have been identified and documented. Such risk factors include, but are not limited to, the following:
- **a.** anatomic structures of the gastrointestinal tract that impair digestion and absorption;
- **b.** neurological disorders that impair swallowing or chewing;
- **c.** diagnosis of inborn errors of metabolism that require food products modified low in protein (for example, phenylketonuria (PKU), tyrosinemia, homocystinuria, maple syrup urine disease, and proprionic aciduria methylmalonic aciduria);
- **d.** prolonged nutrient losses due to malabsorption syndromes or short-bowel syndromes, diabetes, celiac disease, chronic pancreatitis, renal dialysis, draining abscess or wounds, etc.;
- **e.** treatment with anti-nutrient or catabolic properties (for example, anti-tumor treatments, corticosteroids, immunosuppressants, etc.);
- **f.** increased metabolic and/or caloric needs due to excessive burns, infection, trauma, prolonged fever, hyperthyroidism, or illnesses that impair caloric intake and/or retention; or
- **g.** a failure-to-thrive diagnosis that increases caloric needs while impairing caloric intake and/or retention.

4. A comprehensive medical history and a physical examination have been conducted to detect factors contributing to nutritional risk.

5. Enteral nutrition is indicated as the primary source of nutritional support essential for the management of risk factors that impair digestion and/or malabsorption, and/or for the management of surgical or pre/post- operative preparation.

6. A written plan of care has been developed for regular monitoring of signs and symptoms to detect improvement in the member's condition. Nutritional status should be monitored regularly:
- **a.** for improvements in anthropometric measures;
- **b.** for improvements in laboratory test indicators; and
- **c.** in children, to assess growth and weight for height.

B. Noncoverage Criteria

MassHealth does not consider enteral nutrition products to be medically necessary under certain circumstances, which include, but are not limited to the following.

1. A medical history and physical examination have been performed and other possible alternatives have been identified to minimize nutritional risk.

2. The member is underweight, but has the ability to meet nutritional needs through the use of regular food consumption.

3. Enteral products are used as supplements to a normal or regular diet in a member showing no clinical indicators of nutritional risk.

4. The member has food allergies, lactose intolerance, or dental problems, but has the ability to meet his or her nutritional requirements through an alternative food source.

5. Enteral products are to be used for dieting or a weight-loss program.

6. No medical history or physical examination has been taken and there is no documentation that supports the need for enteral nutrition products.

Section III: Submitting Clinical Documentation

A. All enteral nutrition products require prior authorization. Requests for prior authorization must be accompanied by clinical documentation that supports appropriate medical use of the product.

B. Documentation from the most recent medical evaluation must include all of the following:
1. the primary diagnosis name and ICD-9-CM code specific to the nutritional disorder for which enteral nutrition products are requested;
2. the secondary diagnosis name and ICD-9-CM code specific to the comorbid condition;
3. clinical signs and symptoms, including anthropometric measures (for example, height, weight, BMI, BMR, growth charts, and prognosis for children);
4. comprehensive medical history and physical exam;
5. risk factors for developing malnutrition (as indicated in Section II.A.3 of these Guidelines);
6. laboratory tests sufficient to establish the diagnosis of malnutrition;
7. route of enteral nutrition treatment;
8. documentation of past and current treatment regimens; and
9. type and estimated duration of the need for enteral nutrition products.

C. Clinical information should be submitted on the MassHealth Medical Necessity Review Form for Enteral Nutrition Products and accompanied by the Prior Authorization Request form. The MassHealth Medical Necessity Review Form for Enteral Nutrition Products should be used in place of the General Prescription form. These forms must be completed by the prescribing physician or clinical staff involved in the member's care. For instructions on the electronic submission of a request for prior authorization, go to MassHealth's Automated Prior Authorization System at www.masshealth-apas.com.

MassHealth bases its determination of medical necessity for enteral nutrition products on a combination of clinical data and the presence of indicators that affect treatment. A new or updated Prior Authorization Request and MassHealth Medical Necessity Review Form for Enteral Nutrition Products must be submitted to continue the use of enteral nutrition products before the expiration of the current approval.

Select References

American Gastroenterological Association. Medical position statement: guidelines for the use of enteral nutrition. 1995. Publication for updated guidelines due fall 2004 pending approval of AGA as of June 14, 2004.

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EAST Practice Management Guidelines Work Group. *Practice management guidelines for nutritional support of the trauma patient*. Allentown, PA: Eastern Association for the Surgery of Trauma. 2001.

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These Guidelines are based on review of the most current medical literature on clinical practice management of nutritional risk. The contents of these Guidelines and references may change or be updated periodically as new clinical evidence emerges.

Effective Date: December 1, 2004 **Approved by:** _____, Medical Director